

REMARKS

Claims 1, 3, 4, 8-30 and 77 are pending. Claims 1, 12, 24, 26, and 27 were amended. The amendment to claim 1 is supported by disclosure throughout the specification, e.g., at page 3, line 9. Claims 12, 24, 26, and 27 were amended to correct typographical errors, correct antecedent basis, and for clarity, as suggested by the Examiner.

Applicants acknowledge the allowability of dependent claim 6. Claim 6 was canceled and rewritten in independent form as new claim 77.

No new matter has been added by this amendment.

35 U.S.C. § 102

Claims 1-2, 5, 7, 9, 13, 19, and 29 were rejected for anticipation by Paul (U.S. Patent No. 5, 531, 989). Claim 1 has been amended to require a *Bacillus coagulans* bacterium. Paul fails to describe a *Bacillus coagulans*; therefore, the rejected claims are not anticipated by Paul.

35 U.S.C. 103

Claims 1, 8, 10-19, 24025, and 30 were rejected for obviousness over Paul.

As is discussed above, claim 1 was amended to require a *Bacillus coagulans* bacterium, and Paul fails to describe such a bacterium. In fact, Paul is limited to Lactobacilli sp. and Bifidobacteria sp. Thus, the amended claims are not obvious over this reference.

Claims 1-4 were rejected over Paul in view of Fukushima. Claim 2 has been canceled, and claim 1 has been amended to require a *Bacillus coagulans* bacterium. Paul is limited to a description of Lactobacilli sp. and Bifidobacteria sp. The Fukushima et al. abstract describes a composition containing a mixture of Bacillus, Lactobacillus, Streptococcus, Saccharomyces and

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Candida species, but fails to describe *Bacillus coagulans*. Because there is no suggestion to administer the particular bacterium required by the amended claims, the claims are non-obvious over this combination of references.

Claims 1 and 19-25 were rejected for anticipation by Paul in view of Bova et al. Bova is cited for a description of compounds and methods for reducing cholesterol. Neither Paul nor Bova describe or suggest administering a composition containing *Bacillus coagulans*, as required by the amended claims. Therefore, this rejection should be withdrawn.

Claims 1 and 26-28 were rejected for obviousness over Paul in view of Mandeville et al. On page 14, lines 4-7, of Paper No. 9, the Examiner states:

one of ordinary skill in the art would have been motivated by Mandeville, III et al. to include a cholic acid complexation (sequestering) agent in the method of Paul with a reasonable expectation of success for reducing serum cholesterol because of the cholesterol/lipid reducing effects as demonstrated by Mandeville, III et al. This rejection is also met by the present amendment. Paul does not describe or suggest *Bacillus coagulans* administered alone or in combination with another composition for reducing cholesterol. Mandeville et al. does not remedy this deficiency. The combination of Paul and Mandeville fail to disclose or suggest a critical element of the amended claims, i.e., *Bacillus coagulans*.

Applicants submit that the present amendment distinguishes the invention from the cited art and therefore request withdrawal of the rejections under § 103.

35 U.S.C. § 112

Claims 12 and 24-28 were rejected for indefiniteness.

The claims were amended for clarity and to correct typographical errors. The rejection under §112 can now be withdrawn.

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CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

A petition for extension of time and a check in the amount of \$460.00 is enclosed to cover the petition fee for a three month extension of time pursuant to 37 C.F.R. § 1.17(a)(3). The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19374-502 NATL.

Respectfully submitted,



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Appendix: Marked up version of claims.

In the claims:

Cancel claim 5- 7. Amend claim 1, 12, 24, 26, and 27. Add new claim 77.

1. (amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is *Bacillus coagulans*.
12. (amended) The method of claim 11 wherein said administering comprises introducing into the digestive tract of from 5×10^8 to 5×10^9 viable [bacterium] bacteria per day.
24. (amended) The method of claim 19, wherein said [fibrin] fiber product is selected from the group consisting of gembibrozil, fenobibrate, psyllium, bran, glucomannan and Jerusalem artichoke flour.
26. (amended) The method of claim 1 wherein said [compost] composition further comprises a cholic acid complexation agent.
27. (amended) The method of claim 26 wherein said complexation agent is a salt of a metal selected from the group consisting of [a metal salt of] calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium sodium, and zinc.

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77. (new) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is Sporolactobacillus P44.